

The claims in the application are claims 1, 8, 11 and 13 to 22, all other claims having been cancelled.

Applicant is submitting herewith a new Abstract of the Disclosure on a separate sheet of paper.

All of the claims were rejected under 35 USC 112, second paragraph, as being indefinite. The Examiner objected to the expression "and/or" and the expression "characterized in that". The Examiner also objected to phrase "such as" and objected to claims 4, 5, 6 and 7 as being indefinite. The Examiner objected to claim 13 as not using the Markush terminology.

Applicant respectfully traverses these grounds of rejection since the amended claims are believed to properly define the invention. Claim 1 has been amended to delete "and/or" from the claim and "wherein" is used in place of "characterized in that" where ever it appears and claim 1 is free of the other objections thereto raised by the Examiner. The cancellation of claims 2 to 10 obviates the rejections thereto. Proper Markush terminology is used therein and the Examiner's suggestion with respect to claim 11 has been adopted. The Examiner's suggestions with respect to claim 13 have been adopted and claim 14 has been amended to be in proper American form. In addition, new claims 16 to 22 have been added which conform with 35 USC 112. Therefore, withdrawal of this ground of rejection is requested.

Claims 1, 2, 5 to 7, 13 and 14 were rejected as being anticipated by the Tanaka et al reference which, according to the Examiner, teaches a health food noodle composition comprising Ganoderma lucidum powder of fungi and chitosan lactic acid solution for cleaning blood which, according to the Examiner, shows a pharmaceutical composition comprising the claimed ingredients of fungi and chitosan so as to render the claimed compositions anticipated.

Applicant respectfully traverses this ground of rejection since the Tanaka et al reference does not anticipate or render obvious Applicant's invention. Tanaka et al relates to a health food composition prepared mainly by molding a mixture of Denshichi ginseng powder as its major ingredient and other products of, for example, tea *Gymnema sylvestre*, Gynostemma pentaphyllum starch, mannan, a root of *Pueraria lobata*, *Zodedtera marina*, *Ganoderma lucidum* and fungi powder with water. The reference makes a wide list of compounds that can be used and enumerates the two ingredients fungi and chitosan in a long list of ingredients.

Applicant does not agree that the claimed compositions are taught or the advantages thereof since the object of Applicant's invention is not a composition containing at least one active substance for any therapeutic purpose but a composition containing as the active ingredient a combination of fungi and chitosan having therapeutic properties and being free of contaminates. Moreover, the Tanaka et al reference contains only 2% of chitosan which is quite different from the 30% to 70% by weight in the present compositions. The amount of 2% can play no role as chelating

agent of contaminants. Therefore, Tanaka et al neither anticipates nor renders obvious Applicant's invention and withdrawal of this ground of rejection is requested.

Claims 1, 3, 8, 12 and 14 were rejected under 35 USC 102 as being anticipated by the Takenaka et al reference which, according to the Examiner, teaches a composition comprising a mushroom extract Agaricus blazei Murr and chitosan which is an anti-oxidation dietary health food product. The mushroom extract is taught as a polysaccharide having cholesterol lowering properties and therefore, teaches the claimed composition.

Applicant respectfully traverses this ground of rejection since the Takenaka et al reference neither anticipates nor renders obvious Applicant's invention. The Takenaka et al reference discloses a health food composition containing stabilized  $\beta$ -carotene and mushroom extract and describes the extraction process of the "mushroom odor" by using a culture of cyanobacterium added to a water solution of agar and 1% of chitosan.

Agaricus blazei Murr is admixed at a temperature of 40°C. The problem solved by Applicant's invention is completely different from that the reference cited by the Examiner. Moreover, the reference composition contains only 1% of chitosan which is quite different from Applicant's 30% to 70% by weight in Applicant's compositions and the amount of chitosan is an important characteristic that defines the specificity of the dietetic mushroom based composition without contaminants. Therefore, the reference neither anticipates nor renders obvious Applicant's invention and withdrawal of this ground of rejection is requested.

Claims 1 and 12 to 14 stand rejected under 35 USC 103 as being anticipated by the Maeda et al reference which, according to the Examiner, teaches a health food product comprising Lentinus edodes, Ganoderma and chitosan. The ingredients are combined, dried and pulverized to obtain a powder which is used as a food additive and the Examiner deems that this is a pharmaceutical composition containing fungi and chitosan.

Applicant respectfully traverses this ground of rejection since the Maeda et al reference does not anticipate or render obvious Applicant's invention. Maeda et al teaches a health food composition containing a lot of ingredients including mushrooms and 1% by weight of chitosan and this is in no way related to Applicant's 30% to 70% by weight of chitosan. The 1% used by the reference is a fiber that has properties allowing it to bind fat and this property has been known for a long time to prevent fat from being absorbed and therefore, acts as a dietary supplement. The chitosan used in Applicant's invention is entirely different in its composition and withdrawal of this ground of rejection is requested.

Claims 1, 2, 6, 7, 12 and 14 were rejected as being anticipated by the Hatanaka reference which, according to the Examiner, teaches a pharmaceutical composition containing fungi and chitosan.

Applicant respectfully traverses this ground of rejection since the reference relates to processing chitosan into an easily digestible and absorbable state for addition to food by mixing an edible acid in an extract of Monascus purpureus in water with chitosan to form a liquid mixture and then can be added to food to provide a fortified food which is allegedly more healthy since it can be absorbed into the body. This is in no way related to Applicant's invention and withdrawal of this ground of rejection is requested.

Claims 1 to 5 and 11 to 14 were rejected under 35 USC 103 as being obvious over the Kato reference taken in view of the Angerere et al reference. The Examiner concedes that Kato does not teach a pharmaceutical composition containing an acid chitosan but deems that it would have been obvious to add an acid chitosan to a composition of fungi and a basic chitosan to provide the claimed pharmaceutical because Angerere et al teaches a composition comprising an acid chitosan that has a beneficial health promoting effect. Therefore, the Examiner deems the composition to be obvious.

Applicant respectfully traverses this ground of rejection since it is deemed that Kato is directed to a food comprised mainly of chitosan enriched and activated D2 and a polysaccharide such a  $\beta$ -glucan extracted from a mushroom such as *Grifola frondosa* and the food contains 40% to 60% by chitosan and 60% and 50% of the *Grifola frondosa*. Applicant's invention is not related to dietary compositions which may contain vitamins such as D3. Therefore, it is deemed that this combination of the prior art fails.

Claims 1, 3, 9, 10 and 14 were rejected under 35 USC 102(e) as being anticipated by the Zaveri patent which, according to the Examiner, teaches an anti-inflammatory pharmaceutical composition comprising a yeast extract and chitosan succinamide and therefore, teaches the claimed compositions.

Applicant respectfully traverses this ground of rejection since the Zaveri patent in no way teaches Applicant's invention. The reference relates to a dermatological healing kit with a pigment stabilizer consisting of 1 to 5% of a mixture of glycerine, butylene glycol, bearberry extract and mitracarpus extract and 0.01 to 1.5% magnesium ascorbyl phosphate and 0.01 to about 5% tricholoma matsutake extract. The pigment stabilizer is combined with an anti-inflammatory emollient. This is in no way directed to Applicant's invention which has to contain 30 to 70% by weight of chitosan and therefore, withdrawal of this ground of rejection is requested.

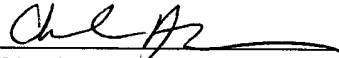
Claims 1, 2, 5, 6, 12 and 14 were rejected under 35 USC 102(a) as being anticipated by the Tianwei et al reference which, according to the Examiner, teaches the composition of a mycelium of penicillin chrysogenum mycelium containing large amounts of chitosan.

Applicant respectfully traverses this ground of rejection since the Tianwei et al reference in no way relates to Applicant's invention and is directed to biosorption of heavy metal ion with penicillin biomass. Applicant's compositions, which are pharmaceutical compositions, do not contain heavy metal ions nor any penicillin

mycelium and this is in no way related to Applicant's invention and withdrawal of this ground of rejection is requested.

In view of the amendments to the claims and the above remarks, it is believed that the claims clearly point out Applicant's patentable contribution and favorable reconsideration of the application is requested.

Respectfully submitted,  
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CAM:ds  
Enclosures

**MARKED UP VERSION OF CLAIMS SHOWING CHANGES MADE**

**Claim 1** (amended) [Fungi-based pharmaceutical and/or] Pharmaceutical dietary composition based on mushrooms which contain as active ingredients at least edible mushroom or part of mushrooms and at least one derivative of chitosan selectd from the group consisting of acidic or cationically substituted chitosan derivatives and basically-substituted chitosan derivatives , in admixture or combination with a non-toxic diluent or vehicle [characterized in that they contain one or more fungi or parts of edible fungi presenting therapeutic properties and chitosan as chelating agent of contaminants such as heavy metals, radioactive metals, weed-killers, fertilizers and insecticides, combined or mixed with a diluting agent or a non-toxic vehicle].

**Claim 8** (twice amended) [Compositions] A composition according to claim [3] 1, [characterized in that] wherein the [basic] basically substituted chitosan derivative has a pH of between 7 and 12.

**Claim 11** (amended) [Compositions] A composition according to claim 1, [characterized in that] wherein the chitosan [contents range] ranges from 30 to 70% by weight [of the total mass] of the composition.



**Claim 13** (twice amended) [Compositions] A composition according to claim 1, [characterized in that] wherein the [fungi] mushrooms are selected from [among:] from the group consisting of [Armillara Mellea, Agaricus bisorus] Armillara Mellea, Agaricus bisorus, Boletus eduli, Cordyceps sinensis, Coriolus versicolor, Flammulina velutipes, Ganoderma lucidum, [Hericim erinaceus,] Hericim erinaceus, Hypsizygus marmoreus, Auricularia auricula-Judae, [Phellinus linateus,] Phellinus linateus, Pleurrotus ostreatus, Grifola frondosa, Agaricus campestris, Lentinus edodes, [Tremela fuciformis,] Tremela fuciformis, and [Volvaria volvacea] Volvaria volvacea.

**Claim 14** (twice amended) [Use of the compositions according to claim 1, with a view to the achievement of a dietary and/or pharmaceutical preparation suitable for combatting] A method for treating obesity, [hypercholesterolemia, diabetes, cancer,] memory disorders or asthma in humans [in the form of galettes or biscuits and the like] comprising administering to humans in need thereof an amount of a composition of claim 1 sufficient to treat said conditions.

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**ABSTRACT OF THE DISCLOSURE**

Pharmaceutical dietary composition based on mushrooms which contain as active ingredients at least edible mushroom or part of mushrooms and at least one derivative of chitosan selected from the group consisting of acidic or cationically substituted chitosan derivatives and basically-substituted chitosan derivatives, in admixture or combination with a non-toxic diluent or vehicle.